REMARKS/ARGUMENTS

The Pending Claims

Claims 1, 2, 4, and 6 are pending and are directed to a process for causing a stem cell to differentiate into a cell which expresses surfactant protein C (SPC).

Amendments to the Specification

A substitute specification, as well as a marked-up copy of the substitute specification that shows the changes between the substitute specification and the specification as filed with the referenced patent application, are submitted herewith.

The substitute specification revises the titles of section headings and reorders sections in accordance with 37 C.F.R. § 1.77(b). No new matter has been added by way of the substitute specification.

Amendments to the Claims

The claims have been amended to point out more particularly and claim more distinctly the invention. In particular, claim 1 has been amended to incorporate the features of claims 3 and 5 (now canceled). Additionally, claims 7, 12-16, 18, 19, and 21 have been canceled, since the Office's considers that these claims are directed to a non-elected invention in response to a restriction requirement. No new matter has been added by way of these amendments to the claims.

Summary of the Office Action

The Office makes final the restriction requirement and withdraws non-elected claims 7, 12-16, 18, 19, and 21 from consideration.

The Office objects to the specification as allegedly not conforming to the requirements of 37 C.F.R. § 1.77(b).

The Office rejects claims 1-5 under 35 U.S.C. § 112, first paragraph, for allegedly lacking enablement.

The Office rejects claims 1-6 under 35 U.S.C. § 112, second paragraph, as allegedly indefinite.

The Office also rejects the claims as allegedly anticipated under:

(i) 35 U.S.C. § 102(e) – claims 1-3 and 6 in view of Mollard et al. (U.S. Patent Application Publication 2005/0239201);

(ii) 35 U.S.C. § 102(a) – claims 1-6 in view of Ali et al., *Tissue Engineering, 8*: 541-550 (2002); and

(iii) 35 U.S.C. § 102(b) – claims 1-4 in view of Shannon et al., *Development, 126*: 1675-1688 (1999).

Reconsideration of the objection and rejections are hereby requested.

Discussion of the Objection to the Specification

The Office requires a substitute specification which contains particular section headings in a specific order. Applicants herein submit a substitute specification. In view of the submission, Applicants request the withdrawal of the objection to the specification.

Discussion of the Enablement Rejection

The Office contends that the specification does not enable a method of differentiating *any* stem cell into SPC-expressing cells. The specification describes that the process of the invention can be used to differentiate pluripotent and multipotent stem cells, including adult stem cells, placental stem cells, fetal stem cells, umbilical stem cells, embryonic stem cells, embryonic carcinoma cells, embryonic germ cells, somatic stem cells, bone marrow stem cells, and cord blood stem cells (see, e.g., page 4, lines 12-17, of the originally filed specification). Additionally, the specification provides a working example wherein the inventive process is used to differentiate ES cells into SPC-expressing cells.

As further support that the inventive process can be used with a variety of stem cells, Applicants herein submit a post-filing reference: Berger et al., *Cytotherapy, 8(5)*: 480-487 (2006) (Attachment A). Berger et al. discloses that umbilical cord blood-derived multipotent stem cells can differentiate into cells that express SPC. Berger et al. uses the method described in Ali et al., *Tissue Eng., 8*: 541-550 (2002), which is a scientific publication that is

authored by the inventors and describes the inventive process. In particular, Berger et al. describes using an adherent cell culture in step (a) and SAGM medium in step (b). Thus, Berger et al. demonstrates that, by following the claimed process, stem cells other than ES cells can differentiate into SPC-expressing cells. Furthermore, Berger et al. demonstrates that culture methods other than suspension culture methods can be employed, since Berger et al. uses adherent cell culture.

For these reasons, the claimed process is adequately enabled by the specification. Therefore, Applicants request that the enablement rejection be withdrawn.

Discussion of the Indefiniteness Rejection

The Office contends that the conditions under which a stem cell can be cultured to become an embryoid body and the conditions under which the embryoid body can differentiate into a cell which expresses SPC are unclear. The Office contends that the conditions which would yield the desired results for *any* stem cell would not be apparent to one of ordinary skill in the art.

The pending claims, as amended, recite a process for causing a stem cell to differentiate into a cell which expresses SPC. The process comprises the steps of (a) culturing the stem cell to give an embryoid body, wherein the embryoid body formed in step (a) is exposed to differentiation factors, and (b) culturing the embryoid body in the presence of SAGM medium under conditions which cause the embryoid body to differentiate into cells which express SPC. The recitation that the embryoid body formed in step (a) is exposed to differentiation factors and that step (b) takes place in the presence of SAGM are the only essential features in the differentiation process. This is supported by Berger et al., which describes that the inventive process is suitable for adherent culture and stem cells other than ES cells (e.g., umbilical cord blood-derived multipotent stem cells).

For these reasons, the pending claims are clear, and the indefiniteness rejection should be withdrawn.

Discussion of the Anticipation Rejections

The Office contends that the claims are anticipated by each of Mollard et al., Ali et al., and Shannon et al. These rejections are traversed for the following reasons.

Mollard et al. and Shannon et al. do not teach or suggest culturing the embryoid body in the presence of SAGM medium, as required by the pending claims. Furthermore, Mollard et al. relates to a co-culture method of differentiating stem cells, which differs from the inventive process, and Shannon et al. relates to the production of a cyst, which cannot be considered to be an embryoid body. Since Mollard et al. and Shannon et al. do not teach or suggest each and every element of the pending claims, these references cannot be considered to anticipate the pending claims.

The present application claims priority to GB 0218332.5 filed on August 7, 2002. The present invention, as defined by the pending claims, is described in the aforementioned priority document, which evidences that the present invention was made by the Applicants at least as early as August 7, 2002. In contrast, Ali et al. was not available to the public before August 7, 2002, as evidenced by the accompanying date-stamped contents page of *Tissue Engineering, 8* (2002) (Attachment B). The date-stamp indicates that the relevant volume of the journal was not received by the British Library until October 7, 2002. Accordingly, Ali et al. is not prior art to the pending claims and cannot properly be relied upon to reject the pending claims.

For the above reasons, Applicants request that the anticipation rejections be withdrawn.

Additional Matters

The Office requests that Applicants provide a list of copending U.S. patent applications that set forth subject matter that is similar to the present claims, as well as a copy of claims of such copending U.S. patent applications. Applicants note that there are no co-owned, copending applications.

Conclusion

Applicants respectfully submit that the patent application is in condition for allowance. If, in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is invited to call the undersigned attorney.

Respectfully submitted,

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